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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/629,427	07/29/2003	Michael J. Yaszemski	630666.91012	6019
26710	7590	09/23/2005		
QUARLES & BRADY LLP 411 E. WISCONSIN AVENUE SUITE 2040 MILWAUKEE, WI 53202-4497			EXAMINER MENDOZA, MICHAEL G	
			ART UNIT	PAPER NUMBER
			3731	

DATE MAILED: 09/23/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

10/629,427

Applicant(s)

YASZEMSKI ET AL.

Examiner

Michael G. Mendoza

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 29 July 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-37 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 33-37 is/are allowed.
- 6) ☒ Claim(s) 1-12, 14-26, and 28-33 is/are rejected.
- 7) ☒ Claim(s) 13 and 27 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date 10/16/03

- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

## DETAILED ACTION

### *Claim Rejections - 35 USC § 102*

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claims 1-3, 12, 15, 16, 26, 28, and 31 are rejected under 35 U.S.C. 102(b) as being anticipated by Hadlock et al. 5925053.
3. Hadlock et al. teaches an implant for bridging a gap in a severed spinal cord or nerve and for promoting nerve regeneration, the implant comprising: a matrix comprising a biocompatible, biodegradable, polymeric material and a bioactive agent dispersed within the matrix, the matrix having a proximal end and a distal end (col. 1, lines 50-56; col. 3, lines 10-12; col. 3, lines 27-31); wherein the matrix includes a plurality of internal guidance channels extending between the proximal end of the matrix and the distal end of the matrix; wherein the polymeric material is poly(lactide-co-glycolide) (col. 1, lines 60-63); further comprising Schwann cells disposed within at least one of the plurality of guidance channels; wherein the guidance channels are arranged such that the guidance channels correspond to spinal cord tracts wherein the implant is positioned in a gap in a severed spinal cord (col. 5, lines 21-24); Schwann cells disposed within at least one of the plurality of guidance channels, and a second bioactive agent other than Schwann cells is disposed within at least one of the plurality of guidance channels (col. 3, lines 10-12; col. 3, lines 27-31).

***Claim Rejections - 35 USC § 103***

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. Claims 4-5, 17-19, 30, and 32 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hadlock et al. in view of Juergensen et al. 5736132.

6. Hadlock et al. teaches the implant of claim 1. It should be noted that Hadlock et al. fails to teach wherein the bioactive agent is a proteoglycan degrading enzyme comprising chondroitinase ABC.

7. Juergensen et al. teaches using a proteoglycan degrading enzyme comprising chondroitinase ABC for promoting adhesion of tissue (col. 7, lines 8-23). Hadlock et al. teaches that adherence of tissue is desirable to promote cell growth (col. 1, lines 56-59). Therefore it would have been obvious to one having ordinary skill in the art to include the bioactive agent chondroitinase ABC of Juergensen et al. in the implant of Hadlock et al. to enhance tissue adherence.

8. Claims 7, 14, 20-22 and 29 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hadlock et al. in view of Shastri et al. 6471993.

9. Hadlock et al. teaches the implant of claim 1. It should be noted that Hadlock et al. fails to teach wherein biocompatible, biodegradable, polymeric microspheres including a second bioactive agent are disposed within at least one of the plurality of guidance channels.

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10. Shastri et al. teaches an implant with common microspheres for protecting and controlling the release rate of a bioactive agent (col. 22, line 18-34). Therefore, it would have been obvious to use the microspheres of Shastri et al. to protect the bioactive agent when the implant is being produced.

11. Hadlock/Shastri teaches the implant of claim 7 wherein; the microspheres comprise poly(lactide-co-glycolide) (col. 22, lines 18-34 PGLA); wherein the microspheres are suspended in a carrier (col. 23, lines 31-41)

12. Claims 9-11 and 23-25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hadlock/Shastri as applied to claims above, and further in view of Juergensen et al.

13. Hadlock/Shastri teaches the implant of claim 7. It should be noted that Hadlock/Shastri fails to teach wherein the bioactive agent is a proteoglycan degrading enzyme comprising chondroitinase ABC.

14. Juergensen et al. teaches using a proteoglycan degrading enzyme comprising chondroitinase ABC for promoting adhesion of tissue (col. 7, lines 8-23).

Hadlock/Shastri teaches that adherence of tissue is desirable to promote cell growth (col. 1, lines 56-59). Therefore it would have been obvious to one having ordinary skill in the art to include the bioactive agent chondroitinase ABC of Juergensen et al. in the implant of Hadlock/Shastri to enhance tissue adherence.

***Allowable Subject Matter***

15. Claims 33-37 are allowable over the prior art of record.

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16. Claims 13 and 27 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

17. The following is a statement of reasons for the indication of allowable subject matter: the prior art of record fails to teach or render obvious the overall claimed invention of an implant for bridging a gap in a severed spinal cord or nerve and for promoting nerve regeneration, the implant comprising: guidance channels that are spaced apart adjacent a perimeter of a matrix at a proximal end of the matrix and converge inward toward the axis of the matrix at a distal end of the matrix.

#### ***Contacts***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael G. Mendoza whose telephone number is (571) 272-4698. The examiner can normally be reached on Mon.-Fri. 8:00 a.m. - 5:00 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anh Tuan Nguyen can be reached on (571) 272-44963. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



MM



GLENN K. DAWSON  
PRIMARY EXAMINER